



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/632,947

07/31/2003

Alastair Hodges

104978-172

4975

45416

7590

10/15/2008

LIFESCAN/NUTTER MCCLENNEN & FISH LLP
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1795

NOTIFICATION DATE

DELIVERY MODE

10/15/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/632,947	Applicant(s) HODGES ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 11, 12, 14-20, 22, 24, 27-30, and 42 of U.S. Patent No. 6,638,415 in view of Diebold.

3. As discussed in the previous office actions, all the previous limitations of claims 1-20 were contained in the limitations of claims 1-3, 6-8, 11, 12, 14-20, and 27-30 of the patent. Applicant has amended claim 1 to specify that the presence of a first aperture defining the sidewalls of the cell, and the first and second electrode areas. However, claim 42 of the patent set forth forming an aperture through an electrically resistive material where the aperture defines the sidewall of the chamber. The claims of the patent do not specify that the aperture would define the electrode areas as well. However, Diebold teaches the use of electrode layers whereby

Art Unit: 1795

apertures utilized to form the sensing chamber also define the electrode areas as well. See fig. 1-4 where apertures (8, 17, 35, and 44) are utilized to define the electrode areas. Because allowing the aperture to define the electrode area ensures that the electrodes extend across the entire area of the measurement chamber, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Diebold for the claimed invention of the patent so that the measurement electrodes fill the entire measurement space.

Claim Objections

4. The objection to claim 9 has been withdrawn in view of the amendment to the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/18464 (hereafter “WO ‘464”). WO ‘464 was previously cited by the applicant, but is being relied on for the first time with this office action. The examiner notes that WO ‘464 is in the same family as foreign priority document PCT/AU96/00724, which the instant invention claims priority back to via a number of continuations and continuations-in-part. However, the claims of the instant invention are drawn to a “device for detecting a presence or an absence of a redox

Art Unit: 1795

reactive analyte” (claim 1) where the analyte can include an “antioxidant” (claim 8) or an “oxidant” (claim 10). Furthermore, claim 1 specifies that the device contain a “quantity of reagent sufficient for only a single test”. Neither of these features was set forth in any of the preceding disclosures until the disclosure of application 09/615,691 filed on July 14, 2000. Moreover, most of the mediators of claims 9-11, the buffers of claims 12 and 13, as well as the heating elements of claims 14-16 were never disclosed in the applications preceding 09/615,691. MPEP 201.11 (I)(B) states “if a claim in a continuation-in-part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent nonprovisional application,...such a claim is entitled only to the filing date of the continuation-in-part application”. Hence because none of the parent documents preceding application 09/615,691 disclose an antioxidant or oxidant sensor, disclose a containing reagent for only a single test, or disclose most of the mediators, buffers, and heating elements as set forth in the claims of the instant invention, applicant only has priority for claims 1-20 back to the filing date of application 09/615,691 (filed July 14, 2000) and WO ‘464 qualifies as prior art under 35 U.S.C. 102(b) against the claims. See *Ex parte DesOrmeaux*, 25 USPQ2d 2040 and *In re Chu*, 36, USPQ2d 1089 where parent patents were deemed to be prior art against examined applications despite a claim of priority to those parent patents. Furthermore, see *In re Lukach, Olson, and Spurlin*, 169 USPQ 795 where a foreign patent publication from the same patent family was deemed to qualify as prior art under 35 U.S.C. 102(b) against an application for patent because the application under examination did not have complete support for the claimed subject matter in a grandparent application predating the foreign publication. The latter case citation is precisely relevant for the instant case here because WO ‘464 is a 102(b) teaching

Art Unit: 1795

against the effective filing date of parent application 09/615,691 even though it might not be prior art against any of the applicant's grandparent applications.

7. WO '464 discloses a device for detecting the presence or absence of a redox reactive analyte in an aqueous sample (e.g. glucose in blood), the device comprising an electrochemical cell having one or more walls where the cell comprises a sensing chamber (defined by hole 11), first and second electrodes 13, wherein the first electrode and second electrode are mounted on opposite sides of electrically resistive material 1. See fig. 12 and 14 and p. 7, ll. 17-24. WO '464 further discloses a first aperture 11 extending through the electrically resistive material, the aperture defining a sidewall of the electrochemical cell, a first electrode area of the first electrode and a second electrode area on the second electrode and discloses a second aperture 16 for admitting the sample into the sensing chamber. See fig. 12 and 14; p. 7, l. 11-16; and p. 8, ll. 1-5. WO '464 further discloses a reagent disposed on a wall of the electrochemical cell (p. 8, ll. 21-23) where the reagent is capable of undergoing a redox reaction directly with the analyte to generate an electrical signal indicative of the presence or absence of the analyte. See p. 1, l. 12 through p. 2, l. 5. With respect to the amount of reagent being sufficient for only a single test, although WO '464 does not specify how much reagent is present, enough reagent is clearly present for at least a single measurement. Even if WO '464 contained reagent in excess of what was needed for a single test (e.g. enough for multiple experiments), the claims are constructed with open language (i.e. "comprising", "contains") and the presence of more than the claimed amount of reagent would not read free of the claim.

8. With respect to the electrodes being sensing and counter electrodes, WO '464 discloses both counter and working (i.e. sensing) electrodes. See p. 2, l. 20 through p. 3, l. 2.

Art Unit: 1795

9. With respect to the materials for the first and second electrodes, see p. 10, ll. 7-14.
10. With respect to the use of a reference electrode, see fig. 15 and p. 9, ll. 16-18.
11. With respect to the reagent being capable of oxidizing an antioxidant, WO '464 discloses the use of ferricyanide (p. 3, ll. 3-13), which claim 9 evidences is capable of oxidizing an antioxidant. With respect to the analyte being an antioxidant, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, see the alternative rejection below.
12. With respect to the use of an electrode distance of less than 150 microns, see WO '464 p. 5, ll. 17-21 where the support sheet 1 defining the distance between the electrodes is 100 microns thick.
13. With respect to the use of an interface transmitting voltage or current, see WO '464 fig. 14 and p. 8, ll. 6-13.
14. With respect to the use of a thin layer electrochemical cell, see WO '464, p. 5, ll. 15 and 16.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1795

16. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '464 in view of either Lin et al (USP 6,042,714) or Mulchandani (USP 5,938,917). Lin and Mulchandani are being cited and relied on for the first time with this office action.

17. WO '464 set forth all the limitations of the claim 1 and further identified that the set forth structure could be utilized to detect either oxidizable or reducible species (p. 1, l. 15 through p. 2, l. 3) and thus thereby anticipated the use of the device for oxidant species as well. However, WO '464 did not explicitly teach the use of any reagents useable for an oxidant species. The disclosed Ferricyanide $[\text{Fe(III)CN}_6]^{3-}$ is only useable for analyte that can undergo oxidation. However, both Lin and Mulchandani teach reagents that are useful for the monitoring of oxidant species. In particular, Lin teaches the use of reagents comprising ferrocyanide $[\text{Fe(II)CN}_6]^{4-}$ that are useable for the detection of peroxide oxidant. See the abstract and fig. 2. Mulchandani teaches the use of polymers containing ferrocene units also find utility as reagents for oxidant (i.e. peroxide) sensors. See the abstract and the polymer in col. 4. The iron cyclopentadienyl units are ferrocenes. Because WO '464 anticipated that its sensor structure should find utility to detect oxidant species as well and because both Lin and Mulchandani disclose the use of reagents that permit the detection of chemically and biologically important peroxide molecules, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Lin or Mulchandani for the device of WO '464 so as to provide an assay for peroxide molecules that would only require small aliquots of sample and be less subject to variance or error (see WO '464, col. 3, ll. 17-24).

18. Claims 12, 13 (and claims 8 and 9 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '464 in view of Nankai et al (USP 5,120,420).

Art Unit: 1795

19. With respect to claims 12 and 13, WO '464 set forth all the limitations of the claims, but did not explicitly recite the use of buffer contained in the sensing chamber. Nankai teaches the use of a phosphate buffer for the reagent layer. See col. 4, l. 62 through col. 5, l. 5. Because buffer solutions ensure that the sensor reagents are maintained at their ideal pH levels, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of WO '464 to ensure that the reagent is maintained at a desired operating pH.

20. With respect to claims 8 and 9 in the alternative, WO '464 taught the use of ferricyanide as a reagent which the applicant evidences can be utilized to oxidize an antioxidant. Although WO '464 didn't explicitly recite the detection of an antioxidant, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, even if the examiner were to give the applicant's intended use further due consideration, Nankai teaches that an electrochemical sensor with ferricyanide as the reagent can be utilized as a detector for antioxidants such as ascorbic and uric acid. See fig. 14 and col. 9, ll. 24-54. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of WO '464 so as to either directly detect the presence of antioxidants within a fluid or to construct a sensor that allows one to correct for antioxidant interference in a glucose detector.

21. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '464 in view of Graves et al (USP 5,342,498).

22. WO '464 set forth all the limitations of the claims, but did not explicitly teach the use of a heater for heating the sample. Graves teaches in an alternate electrochemical sensor that the

Art Unit: 1795

addition of a heating element allows the temperature of the sensor and analyte to be precisely controlled (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Graves for the sensor of WO '464 in order to provide a narrower sensor temperature range, which allows for more accurate measurements.

23. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '464 in view of WO 99/46585 (hereafter "WO '585"). WO '585 was previously cited, but is being relied on for the first time with this office action. Because the effective filing date of the instant invention is July 14, 2000 (see the discussion above), this reference qualifies as prior art under 35 U.S.C. 102(a).

24. WO '464 set forth all the limitations of the claims, but did not explicitly disclose the use of a heating element. WO '585 teaches that the prior art sensors of WO '464 (i.e. PCT/AU96/00724) are inaccurate because of the long length of time needed for the sensor reactions to be completed and teaches the use of a heating element to shorten the response time. See p. 1, l. 15 through p. 2, l. 13 and p. 3, ll. 4-11 and note that the referred to PCT/AU96/00724 corresponds to WO '464. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '585 for the sensor of WO '464 in order to speed up the reaction time for measurement without sacrificing accuracy. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to incorporate the teaching of WO '585 into WO '464 because WO '585 explicitly suggested doing so.

25. With respect to the form of the heating element, it can take the form of either an electrical element of an exothermic reaction. See p. 3, ll. 7-11.

Response to Arguments

26. Applicant's arguments filed 6-26-2008 have been fully considered but they are not persuasive. Applicant urges that the examiner position that '420 patent and '979 patent (and hence WO '464) do not disclose all the claimed subject matter of the present invention, while simultaneously stating that WO '464 anticipates a number of claims is completely contradictory. If the disclosure of WO '464 anticipates the claims of the present application, then applicant believes they should be entitled to priority back to Australian application PN 6619 and WO '464 is thereby not prior art against the claims. First, the examiner notes that not all the claims of the present invention are anticipated by the disclosure of WO '464. In particular, claims 10-16 were not anticipated by WO '464. Hence, the disclosure of WO '464 does not fully support the claimed invention and applicant is thereby not entitled to priority back to the application of WO '464. See MPEP 201.11 (I)(B). Second, the issues of claims 10-16 aside, the examiner believes this precise issue of priority and anticipation was dealt with in *In re Lukach, Olson, and Spurlin*, 169 USPQ 795 (hereafter "Lukach") cited above by the examiner in supporting the use of WO '464 against the claims of the instant invention. The Federal Circuit's response is given below.

Appellants have raised a further point. They contend that "[t]here is an inconsistency constituting an inequity in rejecting the claims as fully met by the Hercules British patent under 35 U.S.C. 102, while at the same time holding that appellants cannot obtain the benefit of the filing date of the U. S. counterpart." What they are saying, in terms of the statute, is that if "the invention was * * * described" in the British reference within the meaning of § 102(b), there must have been a "description of the invention" in the corresponding grandparent application within the meaning of the first paragraph of § 112. This argument appears to overlook the law that the description of a single embodiment of

Art Unit: 1795

broadly claimed subject matter constitutes a description of the invention for anticipation purposes (see, e.g., *In re Ruscetta*, 45 CCPA 968, 255 F.2d 687, 118 USPQ 101 (1958)), whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. See, e.g., *In re Ahlbrecht*, supra. There are other apparent anomalies between the requirements for claim-anticipating disclosures and for claim-supporting disclosures. See, e.g., *In re Hafner*, 56 CCPA 1424, 410 F.2d 1403, 161 USPQ 783 (1969).

27. Relating the issues in Lukach to the issues of the instant invention, WO '464 is analogous to the Hercules British patent in that priority to the earlier foreign document was not granted, even though the foreign patent of that document was utilized in a 102 rejection against the claims. The main point in Lukach raised by the Federal Circuit was that there is a distinction between claim-anticipating disclosures and claim-supporting disclosures and if you have the former doesn't necessarily mean you have the latter. Hence, just because WO '464 anticipates a number of the claims does not mean that WO '464 (and application PN 6619) fully supports the claimed invention as well. Applicant further urges that the disclosures of the '420 patent and the '979 patent are "*nearly identical*" (emphasis by examiner) to the disclosure of the present invention. The examiner does not dispute the large amount of overlap between the disclosure of the present invention and the disclosures of the earlier patents. However, the disclosures are not completely identical as the applicant has admitted. More importantly, the *claims* of the present invention are not fully supported by the disclosure from these patents. See the numerous instances highlighted in paragraph 6 of the 1/9/2008 office action (reprinted above as well). Any one of these instances is enough to sever the priority claim back to these patents and thereby sever priority back to application PN 6619. See MPEP 201.11 (I)(B).

28. Applicant's arguments concerning the use of Lin, Mulchandani, Nankai, Graves, and WO '585 appear to rely on the applicant's arguments that WO '464 was not available as prior art

against the claims of the present invention. Because the examiner was not persuaded by these arguments as discussed above, these further arguments are likewise unpersuasive.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795

October 10, 2008